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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,883	12/27/2005	Frederick John Rowell	330499.00040	9715

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,883	ROWELL, FREDERICK JOHN	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 19* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1 – 10 and 19, in the reply filed on November 9, 2006 is acknowledged.

Claims 11 – 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the difference in the affinity-chromatographic strips when placed in the zero standards (A) versus the 10 ng/mL standards of savinase as described in the specification (Example 2). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 recites the phrase "an affinity-chromatography assay system comprising with an immobilised component," which includes incorrect grammar for using both the terms "comprising" and "with."

Claim 1 further recites the phrase "the flowable component is adapted to flow down the dip strip," which does not include that the flowable component can also flow down the "planar surface," if the immobilized component is supported on a planar surface instead of a dip strip.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the terms a "bio-reagent" and a "complimentary bio-reagent," which are vague and indefinite because it is unclear what exactly the "bio-reagent" and "complimentary bio-reagent" encompass. Further, the specification does not adequately

define these terms in order for one of ordinary skill in the art to understand what these terms encompass.

Claim 1 recites the phrase "the flowable component is adapted to flow down the dip strip of high density," which is vague and indefinite because it is unclear what the term "high density" is exactly referring to.

Claims 2 – 10 use the unconventional claim language "characterized in." This should be changed to "comprising" or "consisting of" for clarity.

Claim 2 recites the term "the bulk solution," which lacks antecedent basis.

Claim 3 recites the term "that immunoreagent," which lacks antecedent basis.

Claim 5 recites the term "the flowable phase," which lacks antecedent basis.

Claim 5 recites the term a "bio-polymer," which is vague and indefinite because it is unclear what exactly the "bio-polymer" encompasses. Further, the specification does not adequately define this term in order for one of ordinary skill in the art to understand what this term encompasses.

Claim 7 recites the phrase "the attraction of the flowable component is achieved by a membrane," which is vague and indefinite because it is unclear how exactly a membrane can achieve the "attraction."

Claim 9 recites the terms "the assay," "labeled antigen" and "labeled antibody," which lack antecedent basis.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 7, 9, 10 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisburg (US 6,287,875).

Geisburg teaches an immunochromatographic test strip (affinity-chromatography assay system) comprising an immobilized component containing one member of a ligand-receptor pair (bio-reagent) and a flowable component comprising particles containing the second member of the ligand-receptor pair (complimentary bio-reagent) characterized in that the immobilized component is supported on a dip strip or planar surface and the flowable component is adapted to flow down the strip of high density (see Figures 2-5; column 2, lines 38-67; column 3, lines 1-66; column 4, lines 30-57; column 5, lines 3-25; column 5, lines 6-63; column 8, lines 18-49; column 9, lines 16-19; column 11, lines 9-14; and Example 1).

With respect to Applicant's claim 2, the flowable component comprising the particles is of a higher density than the bulk solution (see column 16, lines 52-67).

With respect to Applicant's claim 3, the members of the ligand-receptor pair comprising the immobilized component and flowable component preferably comprises antigens and antibodies (see column 4, lines 53-57).

With respect to Applicant's claim 4, the flowable component comprising the particles is retained in a discrete volume (see column 16, lines 1-46).

With respect to Applicant's claim 5, the flowable component comprising the particles can include buffers, preservatives, detergents, and ancillary ligand-receptor members (see column 10, lines 26-32).

With respect to Applicant's claims 6 and 7, the immobilized component is attached to a membrane and is attracted to the flowable component via the interaction of specific binding between two members of a ligand-receptor pair (see column 2, lines 48-67; column 5, lines 3-9; column 12, lines 66-67; and column 13, lines 1-26).

With respect to Applicant's claim 9, the test strip performs a competitive assay using appropriate combinations of labeled antigen or labeled antibody with their complementary unlabeled counterparts (see column 3, lines 18-20; column 12, lines 66-67; and column 13, lines 1-26).

With respect to Applicant's claim 10, the label is a fluorescent or colored label (see column 5, lines 22-40; column 6, lines 17-63).

With respect to Applicant's claim 19, the test strip includes the method of use for performing an assay (see Example 1).

Claims 1 – 7, 9, 10 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Markovsky et al. (US 2003/0207442).

Markovsky et al. teach a test device (affinity-chromatography assay system) comprising an immobilized component containing an analyte conjugate (bio-reagent) and a mobile-phase composition (flowable component) containing a complimentary labeled receptor (bio-reagent) characterized in that the immobilized component is supported on a dip strip or planar surface and the mobile-phase composition is adapted to flow down the dip strip of high density (see Figure 1; and paragraphs [0006], [0007], [0009]-[0011], [0041], [0042], [0050], [0053]-[0055], [0058]-[0060], [0063], [0065], [0068], [0070], [0077], [0084], and [0085]).

With respect to Applicant's claim 2, the mobile-phase composition (flowable component) comprising the particles is of a higher density than the bulk solution (see paragraphs [0050], [0084] and [0085]).

With respect to Applicant's claim 3, the analyte conjugate and the complimentary labeled receptor can comprise antigens and antibodies (see Example #1).

With respect to Applicant's claim 4, the mobile-phase composition is retained in a discrete volume (see paragraph [0060]).

With respect to Applicant's claim 5, the mobile-phase composition can include a buffer of optimal pH, a detergent, and a protein, such as BSA (bio-polymer) (see paragraphs [0053]-[0058]).

With respect to Applicant's claims 6 and 7, the immobilized component is attached to a membrane and is attracted to the mobile-phase composition via the

interaction of specific binding between two members of a ligand-receptor pair (see paragraphs [0007], [0009], [0070], [0084] and [0085]).

With respect to Applicant's claim 9, the test device performs a non-competitive assay using appropriate combinations of labeled antigen or labeled antibody with their complementary unlabeled counterparts (see paragraphs [0070], [0084] and [0085]).

With respect to Applicant's claim 10, the label is a fluorescent or colored label (see paragraphs [0054], [0057], and [0062]).

With respect to Applicant's claim 19, the test device includes the method of use for performing an assay (see Example #1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geisburg (US 6,287,875) or Markovsky et al. (US 2003/0207442), as applied to claim 7 above, in view of Yu (US 6,723,500).

The Geisburg and Markovsky et al. references discussed in the 102(b) and 102(e) rejections above teach that the membrane is wettable, but fail to teach that the membrane is also hydrophobic.

Yu teaches test strips containing a plurality of reaction zones that are defined by a hydrophobic barrier. A hydrophobic composition is utilized to separate the hydrophilic reaction zones contained on the matrix (membrane) of the test strip, in order to create a barrier between each of the reaction zones (see column 10, lines 34-65). The reaction zones contain various compositions to test for one or more analytes. In some embodiments, the test reagents are the same in the reaction zones in order to create a multi-use test strip. In other embodiments, the test reagents are different in the reaction zones to assay for a panel or plurality of different analytes (see column 8, lines 28-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a membrane that is both hydrophobic and wettable (hydrophilic) as the membrane in the test device of Geisburg or Markovsky et al. as taught by Yu because Yu teaches the benefit of using a hydrophobic composition on a membrane in order to create a barrier between a plurality of hydrophilic (wettable) reaction zones that each contain a composition to test for one or more analytes of interest.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Deutsch et al. (US 4,235,601);

Eisinger et al. (US 4,943,522); and

Brock (US 2002/0001818).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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